

# **Exhibit 11**

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC. : MDL NO. 2327  
PELVIC REPAIR SYSTEM, :  
PRODUCTS LIABILITY :  
LITIGATION :

- - -

THIS DOCUMENT RELATES TO ALL CASES

- - -

June 27, 2013

- - -

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Continued videotaped deposition of  
PIET HINOUL, M.D., Ph.D. taken pursuant to notice,  
was held at the law offices of Riker Danzig Scherer  
Hyland & Perretti LLP, Headquarters Plaza, One  
Speedwell Avenue, Morristown, New Jersey, beginning  
at 9:19 a.m., on the above date, before Ann Marie  
Mitchell, a Federally Approved Certified Realtime  
Reporter, Registered Diplomat Reporter and Notary  
Public for the State of New Jersey.

- - -

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1 to tissue during the removal process or other  
2 complications related to the removal surgery.  
3 Correct?

4 A. Yes. As with any surgery.

5 Q. You talked about earlier I believe  
6 during your deposition that some patients will have  
7 more major inflammatory reactions or -- strike that.

8 I think you testified earlier that  
9 some patients will have more major inflammatory  
10 reactions from the foreign body, the mesh, than  
11 other patients; is that right?

12 MS. JONES: Object to the form.

13 THE WITNESS: Right. So the way  
14 people respond to a foreign substance, it is like  
15 allergies, it will differ. Certain people are  
16 allergic, certain people are not, some of them are  
17 severely allergic, some are not. So the way people  
18 form a scar from a skin incision, it will differ.  
19 And this is exactly the same what would happen to a  
20 TVT or to a mesh product; scarring may differ from  
21 one patient to another.

22 BY MR. CARTMELL:

23 Q. Has the company ever been able to  
24 figure out which patients will have more major  
25 severe reactions to the foreign body?

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1           A.           No. I don't think. We as a company  
2 have not been able to identify that, nor any  
3 academic groups that we know of.

4           Q.           Is degradation related to the TVT  
5 products a potential complication?

6                       MS. JONES: Object to the form.

7                       THE WITNESS: Degradation of the  
8 tape?

9 BY MR. CARTMELL:

10          Q.           Yes.

11          A.           No.

12          Q.           Did Ethicon know at the time of the  
13 launch that the TVT products, that some patients  
14 would suffer complications making it impossible for  
15 them to have comfortable sexual relations for the  
16 rest of their lives?

17                       MS. JONES: Object to the form.

18                       THE WITNESS: It would have seemed  
19 certainly very unlikely, but, again, theoretically,  
20 it would have been a possibility.

21 BY MR. CARTMELL:

22          Q.           The company knew that. Correct?

23          A.           We anticipated those kinds of risks,  
24 yes.

25          Q.           And the company knew of the

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1 So you try to mitigate to prevent that. That  
2 doesn't mean that it will ever occur or that it has  
3 ever occurred.

4 Q. And so if we look at, for example,  
5 the topic that says, "Degraded mesh leading to  
6 bunching/wrinkling in mesh," has that been  
7 confirmed, to your knowledge, that it actually  
8 occurred leading to exposure?

9 A. Right. So to the best of my  
10 knowledge, with more than a decade of use of these  
11 products and longer, the mesh has never been shown  
12 to degrade.

13 Q. If we look, then you were also asked  
14 about the chart that relates to fistula formulation?

15 A. Yes.

16 Q. And would your answers be the same as  
17 to the hazards that are listed under fistula  
18 formulation -- formation? Let me clarify that.

19 I mean, my question is, has it been  
20 confirmed that the conditions listed under "Hazards"  
21 by fistula formulation actually occurred  
22 specifically listed -- leading to fistula  
23 formulation?

24 A. Formation. I think there's a big  
25 difference between exposure and fistula formation,

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1 A. Correct.

2 Q. So if it had turned out over those  
3 seven years or so that some of these hazards and  
4 harms really didn't apply, you wouldn't have  
5 included them. Right?

6 A. We have to include them, but they  
7 would then get a frequency of zero or very low  
8 frequency. That's why there is a frequency column  
9 that we haven't discussed, but you will find all the  
10 explanation for that on page 26.

11 Q. Now, you talked about the concept of  
12 degradation of mesh. And since you did, I'm just  
13 going to quickly identify a document and ask you a  
14 question about it.

15 - - -

16 (Deposition Exhibit No. T-733,  
17 PowerPoint, "Investigating Mesh Erosion in  
18 Pelvic Floor Repair," 18 May 2011, Bates  
19 stamped ETH.MESH.02589032 through  
20 ETH.MESH.02589079, was marked for  
21 identification.)

22 - - -

23 BY MR. SLATER:

24 Q. It's a document that's now being  
25 marked as Exhibit 733. I promise you this is only

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1 going to take about two minutes, this document.

2 I've handed you what we've marked as  
3 Exhibit T-733. And it's a report that was  
4 commissioned for Johnson & Johnson and Ethicon for a  
5 company named PA Consulting investigating mesh  
6 erosion in pelvic floor dated May 18, 2011. Do you  
7 see this? Do you see the document in front of you?  
8 Correct?

9 A. Yes.

10 Q. What I'd like you to do is turn to  
11 page 35.

12 And this company that was hired by  
13 Johnson & Johnson to do this evaluation concluded  
14 "Polypropylene can suffer from degradation following  
15 implant." And it says just below that,  
16 "Polypropylene has a long history of use but it is  
17 subject to degradation; a process which initiates  
18 after a few days post implantation in animal  
19 studies." And then there's a citation 1 and there's  
20 a reference. Do you see that below?

21 A. I see that, yes.

22 Q. And then a little further down,  
23 actually at the very last bullet point, it says,  
24 "High resolution images of excised meshes clearly  
25 show physical degradation of polypropylene

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1       filaments."   Do you see that?

2               A.       Yes.

3               Q.       And they're citing --

4                       And when they talk about excised  
5 meshes, they're talking about explants.   Correct?

6               A.       So yes.

7               Q.       And they're citing "Images on file,  
8 Prof. Bernd Klosterhalfen."   Do you see that?

9               A.       Yes.

10              Q.       So PA Consulting, as part of this  
11 study, consulted with Prof. Klosterhalfen according  
12 to this study.   Correct?

13              A.       That's what you say.   I don't know.

14              Q.       And Prof. Klosterhalfen is probably  
15 considered to be the pathologist with the most  
16 knowledge in the world on the subject of what is  
17 shown by explanted meshes in this field.   Correct?

18                      MS. JONES:   Object to the form.

19                      THE WITNESS:   Prof. Klosterhalfen is  
20 considered an expert in this field.

21   BY MR. SLATER:

22              Q.       He's considered the foremost expert  
23 in the field.   Correct?

24              A.       I don't know whether you can rank --  
25 I don't know whether there is such a competition



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1 as...

2 Q. You certainly have referred to him as  
3 the, quote/unquote, god of surgical pathology and  
4 acknowledged to me that even though it was somewhat  
5 of a tongue-in-cheek statement, it was a recognition  
6 of his very high stature in the field. Correct?

7 A. Maybe it was ironic.

8 Q. Well, according to this study  
9 commissioned by your company, they documented that  
10 Prof. Klosterhalfen's own study of explanted meshes  
11 showed physical degradation of the polypropylene  
12 filaments. That's what's documented here. Correct?

13 MS. JONES: Object to the form.

14 THE WITNESS: No, because, you know,  
15 all they refer to is an image on file. It's not a  
16 study. Right? That's what it says.

17 BY MR. SLATER:

18 Q. This study, this document I've given  
19 you, cites to Prof. Klosterhalfen's explant study as  
20 evidence that excised meshes, explants, show  
21 physical degradation of polypropylene filaments.  
22 That was documented in Ethicon's and Johnson &  
23 Johnson's records as of May 2011. Correct? You see  
24 it in front of you. I'm not asking you for an  
25 interpretation. That's what's documented. Correct?

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1 A. No, I disagree.

2 Q. You would disagree that the statement  
3 says, "High resolution images of excised meshes  
4 clearly show physical degradation of polypropylene  
5 filaments"? You disagree that I've read the words  
6 accurately?

7 A. Oh, you read perfectly well.

8 Q. And they cite to Prof. Klosterhalfen  
9 as having shown them evidence to support that  
10 statement. Correct?

11 MS. JONES: Object to the form.

12 BY MR. SLATER:

13 Q. That's what's stated right there.  
14 Correct?

15 A. It -- why don't you read what is  
16 stated as a reference.

17 Q. "Images on file, Prof. Bernd  
18 Klosterhalfen." And then the fact that he's in  
19 Aachen. I'm not going to try to pronounce the word.

20 A. I agree that that is what is written  
21 there.

22 Q. So the idea of the mesh material as  
23 documented in this FMEA actually being -- showing  
24 degradation and causing complications as set forth  
25 here described as harm in the FMEA table, there is

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1 evidence in Ethicon's files that that occurs and  
2 I've just shown it to you. Correct?

3 MS. JONES: Object to the form.

4 THE WITNESS: No, no.

5 MR. SLATER: I have no other  
6 questions.

7 MS. JONES: Let me follow up on that  
8 one question.

9 - - -

10 EXAMINATION

11 - - -

12 BY MS. JONES:

13 Q. If you look back at Exhibit -- page  
14 24 on Exhibit 722, under the "Exposure" chart?

15 A. Yes.

16 Q. Which says "Degraded mesh leading to  
17 bunching/wrinkling in mesh"?

18 A. Yes.

19 Q. Have you ever seen that confirmed as  
20 happening in women?

21 A. Absolutely not.

22 MS. JONES: Thank you.

23 - - -

24 EXAMINATION

25 - - -

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1 BY MR. SLATER:

2 Q. Just to be very clear, bunching and  
3 wrinkling of mesh would be -- certainly bunching  
4 would be synonymous with contraction of mesh.  
5 Correct?

6 MS. JONES: Object to the form.

7 THE WITNESS: Not necessarily.

8 BY MR. SLATER:

9 Q. Well, certainly the terms are used  
10 interchangeably by certain people. Correct?

11 A. I would also disagree with that. I  
12 think bunching is -- it could be the way you've  
13 implanted the mesh. You know, if it would have been  
14 not laid nicely flat and for some reason it would be  
15 compressed, that would be crumpling of mesh. So it  
16 may not necessarily have to do with the tissue  
17 contracture around the mesh post-healing.

18 Q. The inflammatory foreign body  
19 reaction that triggers the scarification around the  
20 mesh can lead to bunching or wrinkling of the mesh.  
21 Correct?

22 A. Theoretically, yes.

23 Q. And the larger the inflammatory  
24 response, the more contraction potentially.  
25 Correct?

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1 MS. JONES: Object to the form.

2 THE WITNESS: Potentially correct.

3 BY MR. SLATER:

4 Q. And that could lead to bunching or  
5 wrinkling of the mesh and exposure. Correct?

6 A. Theoretically correct.

7 Q. And what you wrote here on this table  
8 that you attached to your clinical expert report is  
9 that when the mesh degrades, that can lead to  
10 bunching and wrinkling in the mesh and that can lead  
11 to exposure. That's what you wrote on this  
12 document. Correct?

13 MS. JONES: Object to the form.

14 THE WITNESS: Can you repeat and go  
15 slow? Because I think you're jumping.

16 BY MR. SLATER:

17 Q. The FMEA -- rephrase.

18 This FMEA table in this line says  
19 that degradation of mesh leads to bunching or  
20 wrinkling in the mesh which can lead to exposure of  
21 the mesh. That is what is documented there on the  
22 table. Correct?

23 A. No.

24 Q. That's what the words say. Right?

25 A. But I explained to you clearly that

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1 is what can -- we theoretically think could happen.  
2 We then try to mitigate for that hazard. And if it  
3 would occur, it could result in a harm that could  
4 result in a complication. But opposed to that,  
5 you've got to look at what the frequency and the  
6 severity of that complication would be. Okay? So  
7 you have to look at the totality of this harms and  
8 hazards table. So we are not, certainly not stating  
9 that it degrades, that it crumbles and that it is a  
10 complication. That is not what is written in this  
11 table, and that's got to be very clear to the jury.

12 Q. What you told me earlier in this  
13 deposition about this table was absolutely true.  
14 Correct?

15 A. Yes.

16 MR. SLATER: No other questions.

17 MS. JONES: That's it.

18 THE VIDEOGRAPHER: This concludes  
19 today's deposition. Going off the record. The time  
20 is 5:30.

21 (Deposition adjourned at  
22 approximately 5:30 p.m.)  
23  
24  
25